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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,405	10/17/2000	Steven R. Binder	2558B-063700US	3942

20350 7590 10/11/2007

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EXAMINER	
WHALEY, PABLO S	
ART UNIT	**PAPER NUMBER**
1631	

MAIL DATE	DELIVERY MODE
10/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/691,405	BINDER, STEVEN	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *3,4 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-10 and 12-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' remarks, 07/27/2007, have been fully considered. The following rejections and/or objections are maintained, newly applied, or withdrawn for the reasons set forth below. They constitute the complete set presently being applied to the instant application.

STATUS OF THE CLAIMS

Claims 1, 2, 5-10, and 12-22 are herein under examination. Claims 21 and 22 are newly added. Claims 3, 4, and 11 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim.

CLAIM REJECTIONS - 35 USC § 101

The rejection of claims 1, 2, 5-10, and 12-20 under 35 U.S.C. 101 as being drawn to non-statutory subject matter is hereby withdrawn in view of the amendments to the claims.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5-10, and 12-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following rejections are necessitated by amendment.

Claims 1 and 17 are rejected for the following reasons. Claims which are directly or indirectly dependent from claims 1 and 17 are also included as rejected herein, due to said dependence.

Claims 1 and 17 (step a) recite "test data having been obtained." The use of past tense language renders it unclear whether applicant intends for this limitation to be an actual method step, a limitation of the data, or otherwise. Clarification is requested via clearer claim language.

Claims 1 and 17 (step b) recite "reference data sets that were obtained." The use of past tense language renders it unclear whether applicant intends for this limitation to be an actual method step, a limitation of the data, or otherwise. Clarification is requested via clearer claim language.

Claim 17 (step b) recites "subjects known to not have one of said one or more autoimmune diseases." As written, it is unclear whether applicant intends for this limitation to be subject with "no disease", subjects with no autoimmune disease, or something else. Clarification is requested via clearer claim language.

Claims 17 (step c) and 21 recite "suffering from none, one or more of said autoimmune disease." As written, it is unclear in what way a patient can suffer from both "none" disease and "one or more of said autoimmune disease." Clarification is requested via clearer claim language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 12, 13, 14, and 17-20 remain rejected and claims 21 and 22 are newly rejected under 35 U.S.C. 103(a) as being obvious by Zimmerman et al. (Electrophoresis, 1995, Vol. 16, p.941-947), in view of Kim et al. (IDS, filed Jul.10,2006, IEEE Transactions on Pattern Analysis and Machine Intelligence, 1986, p.761-765), and further supported by Anderson et al. (WO/1999/039298; Filed 03/02/1999).

The rejection of newly added claims 21 and 22 is necessitated by amendment.

Applicant arguments that none of the above references teaches reference data sets for "disease-free patients" have been fully considered but are not persuasive for the following reasons.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies ("disease free patients") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). However, to address the amendments to instant claims 1 and 17, Zimmerman clearly teaches a procedure for comparison of autoantibody blots (i.e. data sets) comprising the statistical comparison of any group of staining patterns, and those derived from patients with autoimmune diseases or normal controls, the identification of the bands that contribute most to the differences between such groups, and the determination whether an unknown individual sample belongs to a known group [Abstract]. Their multivariate approach for classifying unknown samples is based on a continuum of "normal" and "diseased" sample sera, wherein each is described by variables representing a particular staining behavior [p.946, Section 4]. Therefore, the Examiner maintains that the above teachings of Zimmerman have been broadly and reasonably interpreted as a teaching for reference data sets that include at least one reference data set associated with none of the specific SADs.

Furthermore, as set forth in the office action mailed 4/30/2007, Zimmerman teaches: Storing blot data obtained from patient serum with autoantibodies associated with known diseases in a computer database (i.e. memory) [Abstract and Sections 2.4.1 and 2.4.2], which is a teaching for a plurality of "reference data" sets as in claims 1 and 17; Obtaining an integrated "Megablot" comprising values associated with myositis (left), myopathy (right) and neither ("0" values) [Fig. 3B, 3C, and 3D], which equates to a teaching for values that are associated with neither disease, as in claims 1 and 17; Comparison of blots of known groups to unknown samples using discriminate analysis [p.944, Col. 2, ¶ 2] and providing a statistically derived

decision as output [p.945, Col. 2 and Table 1], as in claims 1, 17, and 18. Therefore, the Examiner maintains that Zimmerman teaches normal controls or reference data sets (i.e. not of the one or more autoimmune diseases). Regarding newly added claims 21 and 22, Zimmerman teach a computer system comprising software and hardware components for displaying an indication of patient sample associations with SADs [Fig. 3-Fig. 6], as in claim 21. Their method works on any computer system allowing export of data into other applications for further analysis [p.946, Section 4, ¶3], as in claim 22.

For the above reasons, the Examiner maintains that it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the method of Zimmerman et al. using the added feature of a "k-nearest neighbor" algorithm taught by Kim et al., where the motivation would have been to improve automated diagnosis of SLE with a more robust statistical "kNN" procedure [Zimmerman et al., Section 4]. One of ordinary skill in the art would have had a reasonable expectation of successfully combining the above teachings in view of Anderson et al., who teach a decision-support computer system using neural network algorithms to classify and identify patterns in antibody data for disease diagnosis [WO/1999/039298; Filed 03/02/1999, Summary of the Invention].

Claims 1, 2, 5-10, and 12-20 remain rejected and claims 21 and 22 are newly rejected under 35 U.S.C. 103(a) as being obvious by Zimmerman et al. (Electrophoresis, 1995, Vol. 16, p.941-947), in view of Kim et al. (IEEE Transactions on Pattern Analysis and Machine Intelligence, 1986, p.761-765), as applied to claims 1, 12, 13, 14, and 17-20, above, and further in view of Thompson et al. (IDS, filed Jul.10,2006, Lupus, 1993, 2, p.15-19).

The rejection of newly added claims 21 and 22 is necessitated by amendment.

Applicant arguments that none of the above references teaches reference data sets for "disease-free patients" have again been fully considered but are not persuasive for the following reasons.

As applicant's arguments are identical to those set forth above, the Examiner maintains that Zimmerman teaches normal controls or reference data sets (i.e. not of the one or more autoimmune diseases) for the reasons set forth above. Claims 21 and 22 are also rejected for the reasons set forth above.

For these reasons, the Examiner maintains that it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the method of Zimmerman et al. with the added feature of a "k-nearest neighbor" algorithm taught by Kim et al., using the SLE antibody profiles of Thompson et al. to improve automated diagnosis of SLE with a more robust statistical "kNN" procedure [Zimmerman et al., Section 4]. One of ordinary skill in the art would have had a reasonable expectation of successfully combining the above teachings in view of Thompson et al., who suggest methods of statistical analysis applied to SLE data (p.16, lines 31-33).

Provisional Obviousness-Type Double Patenting Rejection

Applicant has not set forth any arguments regarding this rejection. This rejection is therefore maintained and reiterated.

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van*

Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 1-2, 7, 8, and 17 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of co-pending Application No. 10/828,846. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the broadly encompassing scope of the instantly claimed invention causing the inventions to have overlapping embodiments. The instant claims and those of '405 recite the same method steps, with minor variations. For example, claims 1-3 of the application 10/828,846 and instant claims 1-2 of are directed to computer-implemented methods for identifying specific autoimmune diseases using a 'k-nearest neighbor' algorithm. It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to use the appropriate plurality of antibodies and then compare test data and stored reference data using said algorithm to identify disease. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

CONCLUSION

No claims are allowed.

Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1631

MICHAEL BORIN, PH.D
PRIMARY EXAMINER